Expert Report

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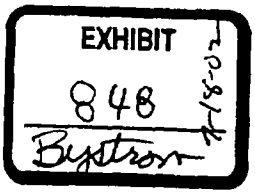
Duramed Pharmaceuticals Inc. vs. Wyeth-Ayerst Laboratories, Inc., Civil Action No. C-1-00-735, In the United States District Court for the Southern District of Ohio



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I. Executive Summary

Drug costs are rising faster than inflation, and becoming a large percentage of the overall healthcare spend. By 2010, it is expected that drug expenditures will be approximately 13.8% of national health expenditures, up from 6.10% in 1995 and 8.2% in 1999.[1]

The distribution of and payment for pharmaceuticals is a complex system involving patients, prescribing physicians, pharmacy providers, managed care organizations (MCOs), pharmacy benefit management companies (PBMs), pharmaceutical manufacturers and wholesale distributors.

The managed health care industry has grown to the point at which the majority of Americans now have some type of drug benefit insurance designed to deliver cost effective pharmaceutical therapy.

The managed care influence on the pharmacy industry has resulted in evolving contractual relationships between pharmaceutical manufacturers, PBMs, MCOs and pharmacy providers. These contractual relationships have influenced physician prescribing choices, and pharmaceutical product market share.

One of the health care industry's largest pharmaceutical manufacturers, Wyeth-Ayerst, dominates a category of pharmaceuticals, known as conjugated estrogens. Wyeth's conjugated estrogen product is called Premarin.

Wyeth leveraged their dominant position of Premarin, with the nation's largest health plans, MCOs and PBMs, to preempt the market entry of Cenestin, a new conjugated estrogen product manufactured by Duramed.

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[1] Heffler, Stephen, et al., "Health Spending Growth up in 1999; Faster Growth Expected in the Future" *Health Affairs*, no. 2, (March/April2001): 194.

II. Scope of Work and Qualifications

Duramed Pharmaceuticals, Inc. has retained me to prepare a report explaining retail pharmacy and pharmacy benefit management companies (PBMs) and their interface within the managed health care industry.

My report will focus on the technical and financial aspects involved in the delivery of pharmaceutical products in the retail pharmacy setting. I will report on the strategic marketing activities implemented by Wyeth-Ayerst Laboratories, Inc. that resulted in Duramed's product, Cenestin, being excluded from the formularies of most managed care organizations in the United States.

My report is based on industry articles I have reviewed together with my own thirty-five years of experience in the retail pharmacy and PBM industries. In preparing my report I have reviewed Wyeth-Ayerst and Duramed documents.

I have not ever testified as an expert in deposition or at trial.

I am a pharmacist licensed in the state of California. I have worked as a pharmacist in numerous retail practice settings. I have functioned in many different positions within a multi-state chain retail pharmacy corporation, including Third Party Administrator and Vice President of Managed Care Services. I have started up a PBM in the state of California for a major chain drug retailer. I played an active role in the implementation of a merger between two national PBMs, after which I functioned as a Co-General Manager of the merged entity. I have been a member of numerous advisory committees for the pharmaceutical industry, in the private as well as the public sector. I have also consulted for several different companies nationally within the health care industry. My background is detailed in the attached curriculum vitae (see **Attachment A**). I am being compensated at the rate of $300 per hour.

III. Pharmacy Industry Background

A. Pharmaceutical distribution system

Multiple entities are involved in the distribution of pharmaceutical products, from manufacturer to consumer. The primary participants in this distribution system are pharmaceutical manufacturers, wholesale distributors, retail pharmacies, mail order pharmacies, governmental agencies, physicians, and pharmaceutical benefit management companies (PBMs).

Manufacturers, such as Pfizer, Wyeth and others, distribute their pharmaceuticals to wholesale distributors, such as Amerisource/Bergen and McKesson, and directly to retail chain, mail order and independent pharmacies. Pharmacies acquire some or all of their pharmaceuticals through drug wholesalers and from pharmaceutical manufacturers. Pharmacies complete the distribution process providing pharmaceuticals to the end user, the patient, upon the written order of the patient's physician.

PBMs enter into pharmaceutical acquisition contracts with manufacturers and pharmacy network contracts with pharmacies to distribute pharmaceuticals to their clients' enrolled members, third party patients. PBMs act as aggregators of pharmaceutical providers and patients providing an efficient delivery system for pharmaceutical products and services.

B. Pharmaceutical payment system

1. Payment cycle for pharmaceuticals

Much like the distribution process for pharmaceuticals, the payment cycle also involves multiple entities in the flow of financials from the patient back to the pharmaceutical manufacturer.

Pharmacy patients can be divided into two categories, "cash patients" and "third-party" patients. Cash patients pay for their prescriptions in total with their own cash out-of-pocket, whereas third-party patients have a health plan or governmental agency paying part or all of their prescription costs.

The payment cycle for pharmaceuticals begins at the pharmacy with the patient and/or patient's health plan, paying the pharmacy their usual and customary retail price, or negotiated contract price, for their prescription.

PBMs function as fiscal intermediaries between a patient's health plan and their pharmacy provider, administering payment to the pharmacy on behalf of the health plan, for pharmacy services provided to their members.

The pharmacy provider pays the wholesaler, or drug manufacturer if they acquired the drug directly from the manufacturer, an acquisition cost for the pharmaceutical products they dispense.

In some cases the drug manufacturer pays a rebate back to the PBM for specific drugs dispensed to their members that are on the PBM's formulary. PBMs usually share a portion of the manufacturer's rebate with their health plan clients.

2. Establishment of acquisition cost for pharmaceuticals

Pharmaceutical manufacturers establish a suggested wholesale price (SWP) for each of their products, unique by strength, dosage form and package size. The average of the SWP prices charged by the national drug wholesalers for a given pharmaceutical product is referred to as the product's "average wholesale price" or, AWP.[2]

AWP is the industry benchmark from which most brand pharmaceutical pricing formulas among PBMs, pharmaceutical manufacturers and pharmacies are derived.

AWP is published and maintained by industry sources such as the "Red Book", published by Thompson Medical Economics, and "First DataBank" of San Bruno, California, the world's leading supplier of healthcare knowledge bases.

Drug wholesalers acquire their brand pharmaceutical products from manufacturers at a discount off of the AWP price, which is then referred to as the "wholesale acquisition cost" or WAC (e.g. AWP-17%).

Pharmacies acquire their brand pharmaceutical products from drug wholesalers at a discount off of the AWP price, usually between 17% and 21%; or directly from manufacturers at their "direct catalog price" (DCP).

PBMs enter into contracts with retail pharmacies with defined reimbursement terms for prescription services provided to their members. Those reimbursement terms reflect a discount off of the brand drugs' cost (e.g. 10% to 17%), plus a dispensing fee (e.g. $1.00 to $3.00)

PBMs also enter into contracts to obtain rebates from the manufacturers in exchange for placement on the PBM's formulary. Drug manufacturer rebates are usually defined as a percentage of the cost of the drug dispensed (e.g. 3% to 15%).

Pharmaceutical manufacturers may also pay administrative fees to PBMs for administering programs that include distribution of their brand pharmaceutical products. These administrative fees are usually defined as a percentage of the AWP price of the manufacturer's brand drugs being dispensed (e.g. 1% to 3%). PBMs usually pass on some of the manufacturer's rebate received to their client, but do not pass on the administrative fee received from the manufacturers.

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[2] American Society of Consultant Pharmacists, WWW.ascp.com/public/ga/awp/awpinfo.shtml, 6/5/00

At the point of service in a retail pharmacy when a patient receives their prescription they pay 100% of their prescription cost if they are a "cash" patient or, if they are a third party patient, they pay a portion of their prescription cost, the copayment, with the remainder of the cost billed to their health plan that subsequently pays the pharmacy.

IV. PBMs

A. PBM Overview

In response to dramatic managed care growth and the resulting unmet need for pharmacy benefit management, specialized companies came into existence to provide prescription drug benefit management for a broad spectrum of customers. These pharmacy benefit management companies, commonly referred to as PBMs, have taken a dominant role in the management of prescription drug benefits.

PBMs originally developed from insurance claim processing and mail order prescription companies to manage their drug benefits. PBMs manage pharmacy benefits for employers, insurance companies, managed care groups, and Medicaid. There are approximately 100 PBMs in the U.S., but the top four companies account for more than 50% of the reported PBM lives.

PBMs may provide administrative services and/or clinical services to their clients. Administrative services include client service, pharmacy network administration, mail pharmacy, claims adjudication, member services, and manufacturer contracting and rebate administration. Clinical services range from formulary management to sophisticated disease management programs.

In general, self-insured employers and insurance carriers outsource both administrative and clinical services to a PBM. Managed Care Organizations (MCOs), including HMOs, and some insurers may elect to retain formulary and clinical control, including manufacturer contracting, and outsource only administrative services, such as claims processing and benefit administration, to a PBM.

PBM services revolve around the drug benefit designed by the client. The benefit design determines the therapeutic categories of drugs that are covered -including whether cosmetic, lifestyle, and over-the-counter (OTC) drugs are reimbursed-and the extent to which generics and formulary drugs are mandated.

PBMs function as aggregators in the pharmacy industry. They aggregate large patient populations through their contracts with health plans, self-insured employers, municipalities, and other clients. These large groups of prescription purchasers provide leverage for the PBMs in their negotiations with pharmacies when contracting for their prescription reimbursement rates.

PBMs also aggregate pharmacy providers to create pharmacy networks for their clients to which their members are directed when needing prescription services. PBMs often leverage participation in their pharmacy network, or potential exclusion from their network, in their prescription reimbursement negotiations with pharmacies for discounted prescription pricing.

PBMs also rely on their large aggregated population groups for leverage when negotiating with drug manufacturers for rebates for their managed care organization

(MCO) clients. These large population groups give the PBMs the ability to influence market share of pharmaceutical products through their formulary process and pharmacy benefit plan design features. Market share is a very important issue to pharmaceutical manufacturers. The rebates pharmaceutical manufacturers pay to PBMs are often tied to the market share of their pharmaceutical products.

The four largest PBMs dominate the PBM industry, collectively administering pharmacy benefit services for over half of the U.S. population. In addition, some larger PBMs "rent" their formularies to smaller PBMs, passing back the rebates that are paid by manufacturers for brand drugs purchased by the smaller PBM's clients' members. This practice of renting out formularies aggregates additional population groups for the larger PBMs to use in their negotiations for rebates from the pharmaceutical manufacturers.

B. PBM Market Consolidation

The PBM market is led by AdvancePCS, Merck-Medco Managed Care, L.L.C. (Merck-Medco), Express Scripts Inc. (Express Scripts), and Caremark Rx, Inc. (Caremark), with the remainder of the market split between smaller PBMs such as Prescription Solutions, insurer owned PBMs such as Wellpoint, and PBMs operated by retail chains such as Walgreens Health Initiatives. It is estimated that the top four PBMs control over 200 million covered lives, more than half the population of the United States. The total number of reported covered lives by PBMs (400,000,000) significantly exceeds the total population of the US, primarily because of double counting. For example, a state government with 3 million members may contract with one PBM for retail services and another PBM to provide mail service. In this case, both PBMs count the same 3 million members.

PBM Market Segments

Segment	Description	PBM	Covered Lives
Tier 1	>20 million covered lives.	AdvancePCS	85,000,000
		Merck-Medco	65,000,000
		Express Scripts	48,000,000
		Caremark Rx	20,000,000
Tier 2 and Retail	Smaller PBMs and those owned by retail chains	New Eckerd Health Services	5,000,000
		Prescription Solutions	5,000,000
		Prime Therapeutics	5,000,000
		Walgreens Health Initiatives	4,000,000
Captives	Insurer-owned PBMs	Wellpoint	30,000,000
		Aetna	5,000,000
Other	Other PBMs		128,000,000
		Total	400,000,000

The four largest PBMs each manage greater than 20 million covered lives, own mail pharmacies, and have extensive retail pharmacy networks with national coverage.

C. PBM services / client contracts

PBMs help to manage pharmacy benefit costs for their clients in several ways, two of the most effective of which are (1) retail pharmacy price discounting, and (2) obtaining rebates from brand pharmaceutical manufacturers.

PBMs develop national pharmacy networks that are under contract to provide prescription dispensing services at negotiated reimbursement rates, offering discounted prices to their client's members. PBMs will often negotiate price discounts with retail pharmacies reflective of the size of the population base represented by their clients' members and the number of competing pharmacies included in the PBM's pharmacy network; the larger the population of members and the more restrictive the pharmacy network, the greater the discount negotiated by the PBM for pharmacy services on behalf of their client.

PBMs offer formulary services to their clients as a cost containment tool. Formularies assist physicians in making cost-effective drug therapy choices. Formularies also attract rebates from the brand pharmaceutical manufacturers which have their products listed on the PBM's formulary.[3]

D. Drug Formularies

Formulary management is the process of developing and maintaining a list of preferred drugs, with the intent of promoting cost-effective clinical care.[4] When multiple drugs exist with similar clinical results, issues such as cost-effectiveness and maximizing manufacturer rebates determine which drugs are included on the formulary. A drug's inclusion on formulary is a prerequisite for that drug to be eligible for rebates from its manufacturer. Formularies are created and administered by PBMs or MCOs.

A formulary is a continually updated list of brand and generic drugs developed by the Pharmacy and Therapeutics (P&T) committee of the PBM or MCO. Formularies often contain relative cost indices for comparable drugs, highlight preferred brands, and include treatment protocols, usage guidelines, and other clinical information. Formularies are typically distributed to primary care physicians, but patients and pharmacists may also receive them. Electronic messages are often returned to pharmacists during claims adjudication indicating formulary status of the drug being dispensed. Formularies are typically produced yearly or every other year, with quarterly updates distributed during the interim.

PBMs use formularies to encourage the use of specific brand (and generic) drugs, which are typically the basis for rebates (and administration fees) paid by pharmaceutical manufacturers. Manufacturers pay rebates to have their brand drugs listed on formularies.

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[3] "Concepts in Managed Care Pharmacy Series: Formulary Management," The Academy of Managed Care Pharmacy, April 30, 1998. www.amcp.org. Link to Concepts in Managed Care Pharmacy.

Clients can develop their own formulary or customize their PBM's national (i.e., standard) formulary to develop one that better meets the needs or preferences of their practitioners and patients. This is typically done by health plans that have their own Pharmacy and Therapeutics (P&T) committee.

When customizing a formulary, PBMs encourage their clients to consider the impact that deviations from the PBM's national, standard, formulary can have on their rebates.

PBMs routinely administer customized formularies on behalf of their MCO clients. Some large MCOs negotiate rebates directly with manufacturers and administer their own rebate programs.

Formulary management services allow a client to use the PBM's formulary and share in the manufacturer rebates. In general, employers and insurers have the least restrictive drug programs and will use their PBM's formulary, while MCO's have the most restrictive formularies and are more likely to develop their own formulary list of approved drugs. Drug formularies can be "open", "incentivized", or "closed".

An **Open Formulary** is a list of recommended or preferred drugs. Under this structure, most drugs are reimbursed irrespective of their formulary status. However, the client's drug benefit plan design may exclude certain drugs (i.e., OTC, cosmetic and lifestyle drugs). Some open formularies may contain patient incentives, such as differential copayments.

An **Incentivized Formulary** applies differential copayments or other financial incentives to influence patients to use, pharmacists to dispense, and physicians to write prescriptions for formulary products.

A **Closed Formulary** limits reimbursement to those drugs listed on the formulary. Non-formulary drugs may be reimbursed if, on an exceptional basis, the drugs are determined to be medically necessary by the health plan.

Physicians, pharmacists, and health plan members are encouraged by PBMs, via mailings, electronic messaging, and other means, to prescribe and dispense formulary drugs. Plan members can also be incentivized financially to use formulary drugs.

Evidence of the prevalence of different formulary types is mixed. About three-fourths of HMOs have preferred or closed formularies (45% preferred or partially closed and 27% closed) (Novartis 1999). There has been a trend away from closed formularies, toward more preferred or partially closed formularies. Health care plans that are more closed systems, such as staff model HMOs; have higher rates of closed formularies (36.4%). In contrast, a survey of employers using PBMs revealed most employers (80%) have open formularies, with only 10% having either a closed or preferred (incentivized) formulary (Wyeth-Ayerst 1999). An explanation postulated in the report for the low use of closed or preferred formularies was that employers value rebates less than unrestricted access and member satisfaction; however, among employers, closed or incentivized formularies are increasing in popularity.

Some PBMs maintain relatively open formularies, but rank drugs of a given therapeutic class according to their cost, usually indicated by dollar signs – one $ for the least expensive, up to five or even six $ for the most expensive. The cost ranking does not necessarily reflect the retail cost of the drug, but its cost reflective of discounts and rebates.

E. Copayment structure description

Cost sharing requirements in prescription drug programs require consumers to pay a portion of the cost of each prescription they obtain. This is referred to as the patient's copayment. As a cost control effort of PBMs, copayments are targeted toward consumers in an attempt to shift some responsibility to them for the cost of their prescription utilization, raise their sensitivity to the cost of that utilization, or to encourage consumers to purchase formulary drugs that earn the PBM lucrative rebates. Effectively, copayment requirements are a component of the benefit structure for prescription drug coverage and thus can vary across health plans managed by a given PBM.

Copayments are also used to provide incentives to encourage the use of generic drugs and formulary brand drugs, which often are the drugs for which the PBM receives rebates from drug manufacturers.

1. Two Tier Copayment Plans:

Traditionally, prescription drug benefits require that the insured pay a minimal copayment, typically $5 for generic drugs and $10 or $15 for brand name drugs. The costs of non-formulary drugs, unless approved by an established exception process, are the responsibility of the patient.[4]

2. Three Tier Copayment Plans:

Increased demand for access to drug products by health plan members and rising pharmacy benefit plan costs for the health plan payors, have resulted in rapid adoption of a three tier copayment plan design.

Three tier copayment plan designs allow non-formulary drugs to be included within a member's drug benefit, which would not have been included in the two tier copayment plan design. The health plan member is charged a tier three copayment amount when a non-formulary brand drug is dispensed within their drug benefit.

The third tier copayment is their plan's highest copayment amount, often sizably more than the formulary brand drug copayment amount, since PBMs want to discourage use of drugs that cut into the market share of their formulary drugs.

Although a three tier copayment plan design allows for non-formulary drugs to be covered by a member's health plan, the member must pay the plan's highest copayment amount to acquire a non-formulary prescription.

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[4] "Managed Care Pharmacy Practice", Robert P. Navarro, Aspen Publishers, Inc. 1999. Page 163.

F. PBM adjudication interface with pharmacy providers

One of the key services PBMs provide is the online adjudication of drug claims from pharmacies commonly referred to as claims processing. This process examines the member's eligibility and drug coverage to determine the pharmacy's reimbursement and member's copayment. In addition, edits are applied to ensure the clinical appropriateness of the drug dispensed and to increase formulary compliance.

The claims adjudication process begins at the point of service at the pharmacy. Upon receipt of the prescription, the pharmacist enters it into the pharmacy computer along with information from the member's drug card. This information is then electronically transmitted, adjudicated, to the PBM's claims processing system.

Once the PBM's claim processing system receives the claim, it is adjudicated and the pharmacist receives a response confirming the member's eligibility and drug coverage, and stipulating the amount the pharmacy is to be reimbursed together with the member's copayment to be collected.

During claims processing, the information submitted by the pharmacy is checked against the health plan's eligibility file to validate the member's name, benefit plan, and birth date. Upon confirming eligibility, the prescription is checked against the benefit design to confirm drug coverage and the corresponding copayment to be paid by the member. The claims processing system also determines the type of network pharmacy submitting the claim (either mail or retail), and calculates the appropriate reimbursement of ingredient costs and dispensing fee for the pharmacy.

The entire adjudication process is usually completed in a matter of several seconds. The PBM claims adjudication process is an on-line real-time transaction, much like a credit card transaction.

G. PBM rebates from pharmaceutical manufacturers

PBM contracting with pharmaceutical manufacturers most often involves negotiations between the two parties to determine positioning of the manufacturer's drug products on the PBM's formulary. Brand pharmaceutical manufacturers enter into rebate contracts with PBMs to maintain, protect or grow market share of their drug products and/or receive information and services from the PBMs. Generic drug manufacturers do not enter into these types of contracts because the PBM does not influence which generic brands are carried at the retail pharmacy.

Formulary positioning and the number of formulary drugs within a drug's product category are key factors which impact the drug's sales volume and market share within its therapeutic class.

In creating a drug formulary the issue of rebates becomes paramount to the PBM when determining formulary positioning between drugs in the same therapeutic class.

1. **Rebates represent a significant component of PBM income:**

   As the PBM industry continues to consolidate the price competition for PBM services is becoming more aggressive. In order for PBMs to attract new clients there must be an incentive for such clients to transition from their existing PBM. These incentives exist as service enhancements and/or lower pricing from the PBMs for their services.

   In the past PBMs have obtained a substantial portion of their profits from claims administration fees charged to their clients for processing the prescriptions of their members. In addition to the claims administration fees PBMs have derived profits from drug manufacturer rebates and administration service fees, clinical service program fees, and differentials in pricing between the amount charged to their clients and the amount paid to their pharmacy providers, for member prescriptions processed.

   As the PBM industry competes aggressively for new clients, the PBM profits derived from their administration fees has diminished and their manufacturer rebates with their associated administration fees have become a more significant component of the PBM's total profitability. For some PBMs brand drug manufacturer rebates and associated fees account for over 50% of their total gross margin dollars. ***This makes drug manufacturer rebates and their associated fees extremely important to the profitability of most PBMs.***

2. **Rebate amount and allocation to the PBM's clients:**

   Rebates and administrative fees are commonly calculated and paid as a percent of the drugs' cost, ranging up to 15%. Rebates greater than 15% are rare, since they might cause manufacturers to exceed their Medicaid Best Price rebates.

   The Medicaid rebate program, established by the Omnibus Budget Reconciliation Act of 1990, was established to help contain government spending on outpatient prescription drugs. Under the basic rebate formula, pharmaceutical manufacturers pay a rebate equal to at least 15.1 percent of the average price they earn on sales to retail pharmacies for brand-name drugs purchased by Medicaid beneficiaries. The basic rebate is often higher than that 15.1 percent minimum because of a "best-price" provision that gives Medicaid access to the lowest price paid by any private purchaser in the United States.

   The best-price provision increases the Medicaid rebate when a manufacturer gives a discount that exceeds the minimum rebate of 15.1 percent. In such cases, the Medicaid rebate is equal to the largest reported discount given to any private sector purchaser. Since Medicaid constitutes about 12 percent of the outpatient prescription drug market, pharmaceutical manufacturers are less willing to give large private purchasers steep discounts because they are required to give Medicaid access to the same low price.[5]

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[5] "Pricing Mechanisms Used By The Federal Government To Contain Prescription Drug Costs", by Anna Cook, Ph.D., Mathematica Policy Research, Inc. *August 8-9, 2000 Leavey Conference Center, Georgetown University, Washington, DC*

The allocation of rebates to a PBM's client is dependent on the client's contract with the PBM. Some large sophisticated clients, such as HMOs, receive all or a fixed percentage of the rebates collected by the PBM. Other clients may receive a guaranteed rebate per prescription claim that the PBM is obligated to provide regardless of the rebate amount actually paid by the manufacturer to the PBM. Some clients may not share in the PBM's rebate at all. Usually the larger the client, the greater the rebate sharing that occurs.

3. Factors influencing rebate levels

There are several factors that may influence the level of rebate provided to the PBMs by pharmaceutical manufacturers for listing their drug(s) on formulary:

1. The number of drug product classes of the pharmaceutical manufacturer's products that are included in the PBM's formulary.
3. The number of individual drug products that are included within each drug product class for the contracting pharmaceutical manufacturer.
4. The degree of control over drug product selection which is afforded by the PBM's drug plan design:
    - **Low control:** The formulary is considered "open" with no prescribing restrictions within the coverage of the member's drug benefit; without benefit designs or financial incentives tied to formulary drug selection.
    - **Medium control:** There are plan design and/or financial incentives tied to formulary drug selection.
    - **High control:** The formulary may be considered "closed" in which case only those products listed on the formulary are included within the member's drug benefit; or, the formulary may indicate certain drugs as "preferred" with substantial plan design and/or financial incentives tied to preferred drug product selection, or financial disincentives associated with the selection of a non-preferred product.

4. Rebates are paid for formulary position, which impacts the market share of the pharmaceutical manufacturer's drug product.

In almost all cases a PBM's P&T committee approval is necessary for a changes to occur on their formulary. P&T committees rarely drive these formulary change decisions; instead they bless decisions made by the PBM's decision makers.

The primary concern of the pharmaceutical manufacturers is that their products are included on the PBM's formulary. They also don't want any negative positioning or financial disincentives for their drugs compared to their competitor's products.

The amounts of the rebates paid vary depending on the contracting abilities of the PBM, the number of covered lives, the pharmacy benefit, and the group's utilization patterns.[6]

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[6] "Managed Care Pharmacy Practice", Robert P. Navarro, Aspen Publishers, Inc. 1999, page 71

V. Retail Pharmacy Industry

A. Pharmaceutical acquisition

Retail pharmacies obtain their pharmaceutical drug products almost entirely from two sources, drug manufacturers (including repackagers) and drug wholesale distributors.

In a report released on August 31, 2001, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) sampled pharmacy acquisition costs for brand name products nationally. The report indicated that retail pharmacies pay an acquisition price to the manufacturer and/or wholesaler that, in aggregate for all brand drugs, equates to AWP less 21.48%.

B. Pharmaceutical reimbursement

Pharmacies purchase pharmaceutical products from wholesalers and drug manufacturers and then sell their prescriptions to patients, most of which have a portion of their prescription costs paid by their health plan, administered through a PBM.

Pharmacies are reimbursed by the PBMs (as a pass through from their clients) for the ingredient cost of the drug dispensed plus a dispensing fee, less the member's copayment. Ingredient cost is based on the lowest of three calculations, depending on the drug dispensed: a discounted AWP, maximum allowable cost (MAC), or usual and customary (U&C). Reimbursement rates vary depending on the client and pharmacy network.

Ingredient cost for branded drugs, with no generic alternative, is typically reimbursed at AWP minus a discount percent (usually between 10% and 17%). Dispensing fees paid for branded drugs are typically $1.00 to $3.00 per prescription.

C. Claims adjudication and formulary compliance processes

There are today approximately 55,000 retail pharmacies in the United States that process between 70% and 90% of their prescriptions on-line through a PBM. There are several key factors which enable retail pharmacies to process prescriptions to a PBM in a real-time environment

1. **Electronic transmission standards and data set definitions:**

The pharmacy industry utilizes a well-defined set of data transmission standards and data field definitions, developed and maintained by an industry-wide standards development organization, The National Council of Prescription Drug Programs (NCPDP).[7]

2. **NDC Number:**

The National Drug Code, or NDC, number uniquely identifies prescription drugs. The NDC number is used to accurately and uniquely identify drugs in the prescription-processing environment. The NDC number is the identifier used by pharmacies when submitting prescription information to a PBM for processing and payment. An NDC number is much like a UPC (bar code) number. It is a 10-digit number assigned by the FDA which uniquely describes a product and its packaging.

3. **Electronic Pharmacy Computer Systems:**

Pharmacies process prescriptions electronically through their pharmacy computer system. As previously described, when a patient submits a prescription to a retail pharmacy to be filled and dispensed, the prescription is entered into the pharmacy's computer system for processing and data warehousing. If the patient has a drug benefit that provides payment coverage for their patient's prescription, the pharmacy adjudicates the prescription information on-line, real-time to the appropriate PBM for processing and payment. The PBM verifies the patient's eligibility and drug coverage, performs numerous checks and edits on the submitted prescription information and returns electronic messages to the submitting pharmacy.

The information received from the PBM by the pharmacy will indicate several things to the pharmacist, such as:

- If the patient is eligible for prescription coverage
- If the submitted prescription is covered by the patient's drug benefit plan
- The patient's copayment amount
- Drug utilization safety messages

4. **NDC Blocks:**

NDC blocks are system edits, administered by PBMs, which are put in place to indicate that a uniquely identified drug is being blocked from coverage within a patient's drug benefit plan. NDC Blocks are sometimes applied to a specific drug within a therapeutic class indicating that drug is not included in the formulary of a patient's health plan.

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[7] NCPDP (National Council of Prescription Drug Programs) is a non-profit, standards development organization comprised of individuals and organization representatives from all segments of the third-party prescription drug program industry.

When a pharmacy submits a drug, which has an NDC block in the PBM's system, it will receive back a "reject code" from the PBM administering the patient's pharmacy benefit. This reject code is an indication to the pharmacy that the submitted drug is not covered by the patient's health plan.

An NDC block is one of the most effective tools the PBM uses to prevent a non-formulary drug from being dispensed to a patient with a drug benefit plan.

5. **Soft Edits:**

Soft edits are advisory messages, returned to the submitting pharmacy from the PBM during the prescription adjudication process. The purpose of a soft edit message is to alert and educate the pharmacist about the prescription being processed.

Often times a soft edit message will alert the pharmacist that there is a drug which is "preferred" by the health plan as an alternative to the drug that was initially submitted by the pharmacist.

The soft edit does not stop the submitted drug from being processed and paid, unlike an NDC block, but rather it suggests to the pharmacist to consider contacting the prescribing physician and recommend an alternative drug to the one originally prescribed. (There may be financial incentives for the pharmacist to contact the physician.)

Soft edits are an effective tool that PBMs use to increase formulary compliance and preferred drug utilization in drug benefit plans that have an open formulary structure.

6. **Prior Authorization:**

Some drugs are indicated on the PBM's formulary as requiring the prescribing physician to obtain prior authorization from the member's health plan before the drug is eligible for payment by within member's drug benefit.

Prior authorizing a drug can be a significant barrier to its being prescribed by the physician and subsequently dispensed by the pharmacy provider. Prior authorizations are a discouragement for the physician to prescribe drugs that are not on formulary. Prior authorizations represent one more "hoop the physician must jump through" to get a health plan to approve payment for a non-preferred drug.

Prior authorization is usually required for the most expensive drugs, especially if there is a cheaper alternative available. Prior authorization is also frequently required even in the case of one-of-a-kind drugs for which there are no alternatives available. In these cases, prior authorization is used to make sure that the drug is not being prescribed for an unapproved use.

The process of obtaining a prior authorization for the physician can range from a relative simple process to a very complex process which may involve step therapy protocols, depending upon the cost of the medication being prior authorized relative to alternative formulary medications within the same therapeutic class of drugs.

A step therapy protocol may require a physician to prescribe older and less expensive drugs in a therapeutic class before prescribing newer and more expensive equivalents.

D. Pharmacy's Relationship with Pharmaceutical Manufacturers

Pharmacy retailers have minimal control over which drug product is dispensed and minimal impact on influencing the market share of a given drug product because up to 90% of drug product selection is directed by formularies or preferred drug lists of PBM clients.

The physician and the member's pharmacy plan design have the largest influence over which drug is prescribed and dispensed. However, there are some measures that retail pharmacies can put in place to positively impact sales and/or market share of a pharmaceutical manufacturer's product, for which the pharmacy may receive some type of reimbursement. The following will illustrate where pharmacies can influence market share movement:

1. Patient compliance programs or "refill reminder letters"
2. Creation of a preferred drug list, which is communicated to their pharmacist(s) and/or supported internally by their pharmacy computer system.
3. Providing promotional/educational information targeted to specific pharmacy customers receiving medications within an identified therapeutic class.
4. Providing educational materials to their pharmacist(s) including specific drug and/or therapy information.

In some instances a pharmaceutical manufacturer may reimburse pharmacies for performing more aggressive measures such as direct patient mailings and/or physician intervention calls to direct drug therapy selection to a specific manufacturer's product.

E. Pharmacy incentive programs

Pharmacies are sometimes approached by brand drug manufacturers and/or PBMs to participate in programs designed to improve the pharmaceutical therapy being provided to their patients. Examples of such programs are:

1. Dispensing compliance programs

Retail pharmacy dispensing compliance programs are often recommended, incentivized, or mandated by the PBM contracted to the retail pharmacy. Some PBM contracts with retail pharmacies require credentialing standards of their pharmacies. Often times such credentialing standards will require a targeted percentage of prescriptions to be dispensed as generic drugs (generic fill rate) as well as an identified percentage of brand drugs dispensed which are on the PBM's formulary (formulary compliance rate). Some PBMs provide financial incentives to their retail pharmacy providers if they achieve a certain level of formulary compliance. The industry's largest PBM, AdvancePCS offers a unique program called the "Performance Drug Program" which administers a payment from drug manufacturers to pharmacists for their efforts in switching a patient's drug

therapy from a "non-preferred" drug to a "preferred" formulary drug of the manufacturer funding the payment.

2. Pharmacist education programs

Depending upon their state of licensure pharmacists must participate in continuing education (CE) programs to qualify for renewal of their pharmacist license (e.g. California pharmacists must complete 30 hours of CE during each 24 month licensure period). Pharmaceutical manufacturers and/or PBMs often times provide CE programs as well as educational materials to pharmacists to improve their knowledge about pharmaceutical therapy as well as specific drug product information. Offering CE credits provides an incentive for pharmacists to participate in the educational programs.

Some pharmaceutical manufacturers also provide pharmacies administration fees to provide educational materials to their pharmacists as well as fees for distributing information to patients and physicians. In these instances the educational materials will pertain to pharmaceutical therapy and/or disease states for which their pharmaceutical products may be prescribed.

VI. Wyeth used rebate contracts with PBMs and pharmacies to exclude Cenestin from the market.

A. Introduction

Wyeth (American Home Products, AHP) is one of the world's largest research-driven pharmaceutical and health care products companies.

Wyeth employs in excess of 52,000 people worldwide, with their Pharmaceutical products division comprised of over 38,000 employees.

In 1999 Wyeth posted sales in excess of $13 billion, listing their total assets in excess of $23 billion. In 1999 Wyeth's Premarin family of products approached sales of $1.8 billion, up 8 percent from year prior. [8]

Wyeth's pharmaceutical products marketing task force is structured into several layers, or divisions. In addition to senior corporate management personnel, these divisions include, area managers, district managers, national account managers and field sales force.

In the United States Wyeth markets their pharmaceutical products and services directly to most all major constituents within the health care industry; pharmacy benefit management Companies, managed care organizations, governmental agencies, physician groups and retail pharmacy organizations.

B. Wyeth's "Preemptive Premarin Plan" to exclude Cenestin

Wyeth entered into extensive rebate contracts with every major PBM and MCO to gain formulary position for their Premarin Family of products, most often at the exclusion of their conjugated estrogen competitor, Cenestin.

Wyeth viewed Cenestin as a challenge to their dominant market share position of Premarin. In February of 1999 Wyeth developed and introduced to their senior management a business strategy called the "Premarin Preemptive Plan". Webster's dictionary definition of "preempt" is "*to seize upon to the exclusion of others*". Wyeth implemented their preemptive plan to seize upon the conjugated estrogen category at the exclusion of Cenestin.

1. According to Wyeth document WYE117998, the objective of their preemptive plan was targeted at Cenestin:

   "Hold Cenestin to <2% TRx share in 1999"

2. Wyeth document WYE117999 identified Wyeth's preemptive strategies:

   - ***"Distance Cenestin from Premarin"***
   - ***"Limit distribution"***
     - ***"Modify Shared Success"***
   - ***"Limit contracting opportunities"***
     - ***"Quantify value of Wyeth contracts"***

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[8] www.wyeth.com

- *"Enforce preferred brand status"*

3. Wyeth's preemptive plan included tactics to modify and accelerate discounts provided to retail pharmacies participating in Wyeth's "Shared Success Program", as described by Wyeth documents WYE118026, WYE118027, WYE118028 & WYE118029.

4. Wyeth's rebate contracts provided significant rebate dollars for PBMs & HMOs if they protected Premarin's market share from competition like Cenestin. Wyeth leveraged their exclusive contracts and rebate dollars to keep Cenestin off their formularies. In addition to entering reimbursement agreements with Advance Paradigm, PCS and IPS, Wyeth also entered into agreements with Health Net and Foundation Health, who utilized PBM services from Advance Paradigm and IPS.

   AdvancePCS is the largest PBM in the industry today, administering pharmacy benefits for 85 million reported lives. AdvancePCS has grown through acquisition by Advance Paradigm of PCS and IPS.

   a. Wyeth document WYE118068, an internal Wyeth memo about a phone call with Advance Paradigm, dated Feb. 19, 1999 states:

      "Our position is protected with API (Advance Paradigm, Inc.) as far as our contractual language regarding Premarin. It reads as follows: 'Premarin, Prempro and Premphase ("Premarin Products") must be listed on the Formulary and Plan Formulary as the sole conjugated estrogen-containing products."

      "Karl wants to identify partnering strategies and tactics on how we can together with API blunt the launch of Cenestin. He spoke of mailings, programs etc. that API would be willing to work with W-A to target the current Premarin users as well as target new Rx's."

   b. Wyeth document WYE118069, an internal Wyeth memo with the subject heading of "Likelihood of Cenestin added to Plan Formularies", dated Feb. 24, 1999 states:

      "Charles- Per your voicemail as far as determining the estimate of plans that will add Cenestin to formularies, the decision will be solely dictated by how Duramed's product will be classified."

      "If the product is classified as a conjugated estrogen we are protected by contractual language for API (Advance Paradigm, Inc.) and NPA (National Prescription Administrators) therefore the percentage will be 0% for both."

   c. Wyeth document WYE118176, an internal Wyeth memo, dated March 26, 1999 states:

      "...In addition we must reinforce those managed care contractual arrangements that identify Premarin as the exclusive conjugated estrogen on formulary."

   d. Wyeth document WEY118386, an internal Wyeth communication regarding IPS and Foundation Health, dated Sept. 14th, 2001, indicates:

"Our contract states that Premarin must be the exclusive conjugated estrogen on formulary"

"Our goal is to restrict Cenestin to either the 3rd tier of a three tier co-pay structure or to non-formulary status regardless of its name."

"Please review this information and use it to formulate a plan for keeping Cenestin in a non-formulary status"

e. Wyeth document WYE118373, an internal Wyeth memo regarding "IPS-Premarin Rebate", dated Feb. 22, 1999, states:

"I have called Kevin Nagle (of IPS) and left him a message regarding Duramed and have asked to meet with him on March 12th. I would like to discuss the possibility of NDC blocking Cenestin in light of our lucrative contract."

f. Wyeth document WYE118385, an internal Wyeth memo to Wyeth's "Foundation Health Systems Team" dated September 14, 2001, recaps a conference call indicating:

"Our contract states that Premarin must be the exclusive conjugated estrogen on formulary"

"Our goal is to restrict Cenestin to either the 3rd tier of a three tier co-pay structure or to non-formulary status regardless of its name"

"Please review this information and use it to formulate a plan for keeping Cenestin in a non-formulary status"

g. Wyeth document WYE118389, an internal Wyeth document referencing discussions with IPS, dated April 11, 1999, states:

"I will be meeting with the account on 4/19 and will discuss the status of 4Q98 rebates as well as the contractual language which prohibits any other conjugated estrogen from formulary status.

I have spoken to Gina Warren, Pharm D., at IPS, who is preparing a monograph on Cenestin and she is aware of the contractual prohibition.

I have asked all other AAMs to meet with their FHS contacts and reinforce the contractual language with the (client)

I am confident, IPS and FHS will comply with the contract and Cenestin will remain non-formulary. Adjustments on rebates would be an additional enhancement to their contractual compliance."

h. Wyeth document WYE118351, an internal Wyeth memo regarding a meeting with Health Net, dated Sept. 14, 2001, states:

> ***"Alan is aware of the exclusionary language in our contract and given the limited indications for the Cenestin product, did not see a role for it on formulary."***
>
> ***"The product (Cenestin) will be blocked in the two tiered copay plans upon launch, and unless P&T has some reason to add it (like a difficult to refuse deal from Duramed) Alan said it would stay blocked and not available."***

i. Wyeth document WYE117146, an internal Wyeth memo regarding Kaiser and Foundation Health Plan, dated May 4, 1999, states: ***"Key Issues:***

> ***"'Value' of Premarin contract in face of Cenestin and decreasing market share in key accounts."***
>
> ***"Contracting language prohibiting any other conjugated estrogen needs to be communicated to all plans."***

j. Wyeth document WYE118379, an internal Wyeth memo dated Sept. 14, 2001, regarding a meeting with IPS on 3/12/2001 states:

> ***"Kevin left a message for the Duramed account manager while I was present and he intends to be as helpful as possible in identifying the risks we might face with this new market entry. I did discuss both Health Net's and Intergroup's slipping Premarin market share and the risk of lost rebates...They both agreed that formulary position would possibly violate the contract language if it (Cenestin) is launched as a conjugated estrogen; at the very least formulary position would erode market share even further. Until a specific plan requests the product or a P&T review occurs, the product will be non-formulary and listed as 'NDC not covered'."***

k. Duramed document DUR000035, a "Viking – Managed Care Update" to Duramed on a June 1999 meeting with PCS indicates:

> ***"The Wyeth-Ayerst agreement bundles oral contraceptives and Premphase and Prempro with Premarin. A negative decision by PCS on Premarin would result in the loss of revenue from these products as well."***

l. Wyeth document WYE154418, an internal Wyeth memo discussing rebate strategy for IPS, indicates:

> ***"If we can adjust the Baseline on a quarterly basis we will have an incentive for IPS and the plans to NDC block Cenestin and where necessary place the product in the highest co-pay category..."***

m. Wyeth document WYE117191, an Internal Wyeth memo dated February 28, 1999, indicates "February Highlights":

"Review Premarin baseline level for Key FHS plans and determine best strategy for preserving value"

n. Wyeth document WYE118373, an internal Wyeth memo dated Feb. 22, 1999 regarding "IPS-Premarin Rebate" states:

"If we can adjust the Baseline on a quarterly basis we will have an incentive for IPS and the plans to NDC block Cenestin and where necessary place the product in the highest co-pay category."

o. Wyeth document WYE118389, an internal Wyeth memo dated April 11, 1999, regarding IPS rebates, indicates:

"Adjustments on rebates would be an additional enhancement to their contractual compliance"

p. Wyeth document WYE118068, internal Wyeth memo dated February 19, 1999 indicates their confidence regarding Premarin being the sole conjugated estrogen on Advance Paradigm's formulary:

"Our position is protected with API as far as our contractual language regarding Premarin. It reads as follows: Premarin, Prempro and Premphase ('Premarin Products') must be listed on the Formulary and Plan Formulary as the sole conjugated estrogen-containing products."

(Wyeth was able to exclude Cenestin from Advance's formulary until its contract expired in December of 2001. Cenestin was subsequently added to AdvancePCS' formulary, on February 4, 2002.)

5. Wyeth's plan was to protect Premarin's market share and prevent Cenestin from appearing on the formularies of the largest PBMs/HMOs that control the majority of health plan members in the U.S.

Below are examples of Wyeth's contracting tactics with Medco, the nation's 2nd largest PBM reporting 65 million covered lives today.

a. Wyeth document #WYE118176, an internal Wyeth memo, dated March 26, 1999 states:

1. ***"The approval of Cenestin is a significant challenge to our women's health care franchise..."***
2. ***"...we must reinforce those managed care contractual arrangements that identify Premarin as the exclusive conjugated estrogen on formulary."***

b. Wyeth document #WYE117254, an internal Wyeth memo dated May 10, 1999, defining opportunities with Medco, states:

"My impression is that we can gain the following by making the change as defined above; (1) Cenestin placed on 'prior authorization' and..."

c. Wyeth document WYE012691, page 9 of Wyeth's amendment dated January 1, 2000 to Medco's Pharmacy Supply Agreement dated October 1, 1995, states:

"Wyeth-Ayerst shall pay an additional Premarin/Prempro/Premphase Market Share Rebate to Medco each Contract Quarter in an amount equal to 0.75% of the Medco mail service volume of Premarin/Prempro/Premphase for such Contract Quarter for each 10% or portion thereof that the Medco Mail Service Market Share of Cenestin....is below the National Market Share of such Products for such Contract Quarter."

d. Wyeth document WYE117253, an internal Wyeth memo about a meeting between Wyeth and Medco, dated May 10, 1999 states:

"The purpose of this meeting was to evaluate current programs and to discuss tentative plans for moving forward. Each party came to the meeting with their list of needs. Objectives I established for this meeting included; (1) Gain commitment to make Cenestin "non-formulary drug" as per contract Premarin is the "exclusive conjugated estrogen on formulary and the preferred oral estrogen therapy."

"After reviewing our contractual arrangement for Premarin, Art agreed that Premarin is the sole conjugated estrogen per terms of the contract. Art will talk with Glen Taylor to determine if "prior authorization" can be put in place for Cenestin."

e. Wyeth document WYE117152 & WYE117153, an attachment "April Monthly Highlights" attached to an internal Wyeth memo dated May 5, 1999, states:

"Cenestin has not been reviewed at present. I believe Wyeth can be successful in getting Medco to take some very positive actions but we will need to redefine Premarin goals in the current Agreement."

6. Wyeth's existing rebate contracts with the largest PBMs/MCOs required that Premarin be the sole conjugated estrogen on their formularies. Wyeth considered it a breach of their rebate contract by the PBMs/MCOs if they were to allow Cenestin on their formularies. Wyeth enforced their contracts to prevent Cenestin from appearing on the formularies. Wyeth notified Express Scripts, the third largest PBM in the U.S. with over 35 million reported lives, that it was a violation to their agreement to list Cenestin on their formulary or on the formularies of their clients.

   a. Wyeth document #WYE118139, an attachment to an internal Wyeth memo, dated March 9, 1999 illustrates Wyeth's dominant formulary position with PBMs & HMOs:

Wyeth had exclusive conjugated formulary status for Premarin with 10 PBMs/HMOs representing 142+ million members.

Wyeth had preferred oral estrogen formulary status for Premarin with 10 PBMs/HMOs representing 169+ million members.

b. Wyeth document WYE117064, an internal Wyeth memo regarding Wyeth's formulary relationship with Express Scripts, ValueRx/DPS dated Nov. 4, 1999, states:

"Express Scripts accepted Cenestin as part of their Bid Grid. Upon our objection, they notified Duramed that they would NOT accept a contract on the product."

c. Viking Document VK0108, a letter from Express Scripts to Duramed, dated Nov. 4, 1999, states:

"Please let this letter serve as notification that Express Scripts, Inc. (ESI) has chosen not to contract with Duramed Pharmaceuticals, Inc. as a result of the 2000 Bid Enhancement process."

"When we requested your bid, we didn't realize there was a pre-existing relationship with Wyeth-Ayerst that prevents us from entering into a contractual relationship with Duramed at this time. For consistency, we will be unable to contract with you on the Diversified Pharmaceutical Services, Inc. (DPS) side as well. We are very sorry that we didn't realize this sooner."

d. Wyeth document WYE025546, an internal Wyeth memo, dated Nov. 9, 1999, states:

"A signed agreement with Duramed, which had added Cenestin to the Express Scripts formulary, was reversed by quick, concerted action between national account sales and CD&A. To date, no known managed care accounts have Cenestin on formulary.

e. Wyeth document WYE051073, Wyeth's "Managed Care National Accounts Action Steps", instructs Wyeth employees:

"-Continue to position Premarin Family as preferred ERT/HRT agents at each National Account

-Ongoing evaluation of each National Account relative to performance and rebates

-Enforce terms of contract"

f. Wyeth document WYE051074, Wyeth's "Premarin Defense Strategy", instructs Wyeth employees:

"Key Financial Implications -Contract & Impact on rebates"

g. Duramed document DUR000037, Viking's Managed Care Update on Cenestin memo to Duramed regarding their November 1999 meeting with Express Scripts / DPS, states:

"Following review for the 2000 formulary program, Cenestin was initially placed in a preferred position along with Premarin. However, shortly after notification was sent to the manufacturers announcing the decision, Wyeth-Ayerst brought to the attention of Express Scripts a pre-existing agreement they had in place with Express which prohibits the addition of any other conjugated estrogen products to their formulary. This agreement was overlooked by Express during the review process, and they subsequently reversed their decision and decided against the addition of Cenestin."

h. Wyeth document WYE023598, an internal Wyeth memo, dated July 20, 2000, states:

" I met with Jim Hill on Tuesday, July 18th to discuss a number of topics."

"First on his list was Premarin. He started out by saying that they had a small but persistent group of clients who were insisting on having Cenestin available and he "needed" to renegotiate the contract. I replied that under no circumstances would we agree to do this and reminded hi that they are receiving over $40 million in rebates per hear that would be at risk."

7. Wyeth communicated to their clients that a breach of their rebate contract would result in Wyeth not paying rebates on Premarin and /or all Wyeth products.

a. Wyeth document WYE157990, an October 6, 1999 letter from Wyeth-Ayerst to Rocky Mountain HMO states:

"According to the terms of the MedImpact Agreement, should Rocky Mountain HMO add Cenestin™ to its formulary or take any action against our oral contraceptives, we will exercise the thirty (30) day no cause termination option in the agreement, and inform MedImpact that Rocky Mountain HMO is no longer eligible to participate in the MedImpact/Wyeth-Ayerst Reimbursement Agreement."

b. Wyeth document WYE157987, An Dec. 14th, 1999 letter from Rocky Mountain Health Maintenance Organization to Wyeth-Ayerst states:

"RMHMO is seriously concerned about the statements made in your letter regarding Wyeth-Ayerst exercising a 30-day no cause termination option if RMHMO adds Cenestin™ to its formulary or takes 'other action' against Wyeth-Ayerst oral contraceptives. We are all well aware of the large market share Wyeth-Ayerst has with its Premarin Family in that category of pharmaceuticals. We seriously question the appropriateness and legality of Wyeth-Ayerst's attempt to use such market share to influence RMHMO's decisions with regard to its formulary for other pharmaceutical products."

8. As part of their "Premarin Preemptive Plan" Wyeth developed a "Cenestin Impact Model" for their national account representatives to share with their PBM/HMO clients. Wyeth's Cenestin Impact Model illustrated and quantified to each

PBM/MCO the value of their contract that would be at risk if they were to add Cenestin to their formulary.

a. Wyeth Document WYE117955, Internal Wyeth memo dated Feb. 3, 1999 from Kevin Wlazelek to Charles Schneider states:

"Charles, the attached Excel files include directions for use, key assumptions, summary, and detail sheets pertaining to all national accounts. Please be advised that each National Account Manager has been mailed a similar account specific file."

b. Wyeth document WYE117988, & WYE117989, attachments to an internal Wyeth memo dated February 9, 1999 from Pat Organsky to Charles Schneider indicate:

"Premarin Defense Cost Tools: Cost Acquisition Model and Managed Care Cost Analysis (Demonstrates Value of Wyeth-Ayerst Contract)"

9. The Cenestin Impact Model clearly illustrated to the PBMs/HMOs the loss of Wyeth rebate dollars that would occur if they placed Cenestin on their formularies with a resulting in a loss of market share for Premarin. Not only did Wyeth demonstrate loss of rebate dollars for their Premarin product, the Cenestin Impact Model communicated a potential total loss of rebate dollars for all Wyeth products, which would result from allowing Cenestin on their formularies.

a. Aetna document AT00264, was a "Managed Care Cost Analysis" which illustrated a potential loss of over $3 million if ***"Business Shifted to Cenestin (market share)"***

b. Wyeth document WYE118080, an internal Wyeth memo dated March 8, 1999 illustrated the fact that the Cenestin Impact Model went out to all of Wyeth's National Account Managers:

"The attached Excel files include directions for use, key assumptions, summary, and detail sheets pertaining to all national accounts. Please be advised that each National Account Manager has been mailed a similar account specific file."

c. Wyeth document WYE118196, a draft memo from Wyeth to Wellpoint dated April 6, 1999 conveying Wyeth's Cenestin Impact Model to WellPoint, as well as reminding WellPoint of their exclusive agreement for Premarin:

"I have enclosed some documents which might serve as a good discussion point for us regarding the market entry of Cenestin, Duramed's new 'synthetic conjugated estrogen, A'. It probably makes sense for us to schedule an appointment so we may discuss this issue further, but in the meantime I thought it might be helpful for you to review the model and determine how it might be of use to you in your analysis."

"For your consideration, our contract dated October 1, 1996, includes language which pertains to this issue. Page 10, Section HB I states 'Premarin, Prempro and Premphase must be listed on the Formulary and Plan Formulary as the sole conjugated estrogen-containing products...."

d. Wyeth document WYE118323, an internal Wyeth memo dated April 13, 1999 spoke about the upcoming meeting between Wyeth and Prescription Solutions indicating preparations being made for a "Showdown":

"Wish me luck…I have three meetings at Prescription Solutions Attached is one of several documents I have prepared for my 'show down'."

e. Wyeth document WYE118325, attached to the above Wyeth memo, dated April 13, 1999, indicates:

"Contract Language: Exhibit A, Section II A: (page 24 of 33)

Premarin, Prempro and Premphase ('Premarin Family') must be the sole conjugated estrogen-containing products listed on the Formulary and all Health Plan Formularies with a co-pay no less favorable than any branded product in this therapeutic category."

"Estimated Economic Impact*:

- ***Premarin Family market share of less than 70.0% results in no rebates:***
- ***An 8% drop in the Premarin Family market share would result in an annual loss of rebates in the amount of $3.7 million***
- ***A 50% drop in the Premarin Family market share would result in an annual loss of rebates in the amount of $3.06 million"***

f. Wyeth document WYE118331, an internal Wyeth memo to Wyeth's "Prescription Solutions Team", dated August 6, 1999, states:

"It is imperative that when you meet with your Regional Pharmacy Directors you confirm NDC blocks are in place. This account can NOT afford to loose any market share to Cenestin!"

g. Wyeth document WYE132292, part of Wyeth's Premarin Preemptive Plan, indicates:

"Quantify the value of Wyeth contract

i. ***Example: <u>Pacificare</u>***

1. ***4.5 million members***
2. ***Premarin Family rebates > $3.8M***
3. ***All other Wyeth product rebates > $3.3M"***

h. Prescription Solutions document RxS0064, an internal Wyeth memo, dated May 10, 2001, states:

"I know we briefly addressed this yesterday, however, it would be my assessment that it is a violation of the contract adding one more agent in this category, but before communicating to Bob T. wanted obtain your feedback."

i. Prescription Solutions document RxS 0662, a subsequent memo from Andrew Marbach of Wyeth to Robert Taketomo of Prescription Solutions, dated May 11, 2001, states:

"As you can see from the attachments, my management feels that the addition of Cenestin to the formulary is a violation of the Reimbursement Agreement per the language on page 24 / Section II / Paragraph A of the agreement. Before you to forward with this, I think it would be prudent to have a discussion on this issue. I will be at your offices on May 17th..."

10. In some instances, where Wyeth felt Premarin's exclusive formulary position was at risk with a PBM/HMO client, Wyeth revised their agreement to increase the rebate dollars paid to the client and lowered the market share performance requirement for their client to achieve the increased rebate amounts.

    a. Wyeth document WYE118320, an internal Wyeth memo dated February 24, 2999, indicates:

    "At our Fast Start meeting in Dallas Bob Repella stated the importance of us being able to amend our national account contracts so our clients' Premarin performance parameters would be adjusted according to changes in the National Premarin performance. We had discussed trying to make this offer not appear as a defense strategy to the market entry of Cenestin – which will require that we do something quickly"

    b. Wyeth documents WYE000036 & WYE000037, an internal Wyeth memo with "Pricing Committee Meeting notes of Oct. 27, 1998" regarding Aetna/US Healthcare indicates:

    "Reestablish the Premarin Family rebates schedule, which was applicable in 1997 with some revision..."

    "In turn for the concessions Aetna would:

    Assure that the Premarin Family products are the sole multi-estrogen component EHT/HRT products listed in the formulary."

    c. Wyeth document WYE032576, an internal Wyeth memo undated, states:

    "Charles explained to the Pricing Committee in 1997 Aetna received rebates for Premarin @ 3%. With the signing of the new contract, Wyeth-Ayerst took those rebates away. Charles proposed if Aetna agrees to include additional language regarding blockage of Cenestin, then Wyeth should in turn reinstate the 3% Premarin rebates. The addition of this language should/could help/maintain our current market share. This was approved by the Pricing Committee."

    d. Wyeth document WYE032575, an internal Wyeth memo dated July 1, 1999, states:

    "We just had a meeting with regards to Aetna's fourth quarter 1998 payment. The dollar increase with the new amendment comes in around $800,000."

    e. Wyeth document WYE03310, an internal Wyeth memo dated July 22, 1999, states:

    "The rational for the creation of a revised HRT/ERT addendum is as follows:

    - ***To motivate MVP into closing the HRT/ERT category by designating the Premarin Family as 'sole conjugated' estrogen***

products and thereby preventing Cenestin from gaining formulary status."

f. Duramed document DUR010786, a Viking Managed Care Update submitted 11/99, states:

"I did speak with Dan concerning Caremark's decision regarding Cenestin and/or Premarin before he left 11/12/99. Based on Wyeth's last proposal it appears that they will go with Premarin. Dan said that the contract would net Caremark more than $1,000,000 in profits annually." Wyeth's contract with Caremark was not only very lucrative for Caremark placing Wyeth's products on their formulary; it required Premarin to be the sole conjugated estrogen on Caremark's formulary.

g. Wyeth document WYE051532, an internal Wyeth memo dated January 28, 2999 ranks Wyeth clients relative to their contracts being at risk.

"Contracts at risk represent those National Accounts which received a significantly lower percent Rebate to Gross sales than the average for all National Accounts while achieving a market share that is close to or above the National Market Share." (PROVANTAGE was one of Wyeth's clients listed 'at Risk")

h. Wyeth document WY117941, an internal Wyeth memo dated January 25, 1999, indicates about ProVantage:

"Maren Spangler told me Friday that she had received a voice mail message from someone at Duramed requesting an appointment to present a 'very aggressive' proposal for their upcoming new product. As we have discussed, the concern here is the structure of their evaporating tiers and the fact that they are not earning any Premarin rebates."

i. Wyeth document WYE049692, an internal Wyeth memo dated April 13, 1999, indicates about ProVantage:

"The ProVantage Reimbursement Agreement Amendment has been signed and forwarded to Lois Rulli. The effect of the amendment is to roll back the Premarin, Prempro and Premphase baseline rebate level to what is was at the beginning of the contract. It is effective as of 3Q98. Please ask Lois for a copy of the amendment and then you can process the submission you have in house – they should earn Premarin rebates as a result of the amendment."

j. Wyeth document WYE013298, an amendment dated March 16, 1999 which amends the January 1, 1997 Reimbursement Agreement between ProVantage and Wyeth-Ayerst, states:

"That part of Schedule C2 which outlines the Product Performance Rebates for HRT is amended and replaced..."

C. Wyeth devised a program, "Shared Success", targeted at retail pharmacies to gain their support in increasing market share of Wyeth's products. Wyeth entered into "Shared Success Program" agreements with retail pharmacies offering purchase discounts in exchange for increasing the pharmacies' market share of Premarin and other select Wyeth products.

1. AHP document AHP027225, a Shared Success Program Agreement between Wyeth and Alco Pharmaceuticals, Inc. dated September 22, 1998 states:

   "Customer shall use reasonable efforts to increase its market share of Products (Wyeth products – including Premarin)"

2. In April of 1999 Wyeth amended their Shared Success Program Agreement to modify their shared success tiers and provide an initial "acceleration discount" their customers could earn by further supporting the utilization of the Premarin Family as described in documents AHP092756 through AHP092759.

   Additional discounts could be earned through further supporting the utilization of the Premarin Family by:

   a. ***Communication of Premarin information to their pharmacists***

   b. ***Providing continuing education programs to their pharmacists on hormone replacement therapy, provided by Wyeth.***

   c. ***Assuring Wyeth that there would be no unusual or artificial pricing structure for any estrogen product that would disadvantage any Premarin Family product.***

VII. Conclusion

The distribution and sales of pharmaceutical products is a complex process that is influenced by well-defined contractual relationships between pharmaceutical manufacturers, managed care organizations, health care providers and pharmacy benefit managers.

The single most influential factor within the managed health care industry that can determine the level of success a pharmaceutical brand product will realize, relative to achieving market share, is whether or not the product is listed on the drug formularies of the industry's largest PBMs and MCOs.

Formulary positioning may be considered the "holy grail" among brand pharmaceutical manufacturers. Although formulary positioning does not guarantee successful product sales and market share penetration, lack of formulary positioning can be considered the "death knell" for a brand pharmaceutical product.

Wyeth-Ayerst, one of the world's largest brand pharmaceutical manufacturers, considered Cenestin to be a potential threat to Premarin's dominant position in the estrogen replacement therapy category of pharmaceuticals. Motivated by this concern Wyeth devised and implemented a preemptive strategy designed to exclude Cenestin from the conjugated estrogen market.

Wyeth leveraged their market share dominance and lucrative financial payments to PBMs and MCOs to achieve and maintain exclusive positioning of their Premarin family of products on PBM and MCO formularies dominating the health care market.

Wyeth devised their preemptive strategy not only to insure their Premarin family of products would be listed on PBM and MCO formularies; their strategy also included specific tactics designed to keep Cenestin off PBM and MCO formularies. Wyeth's tactics were both protective and predatory in their effort to maintain market share dominance of the estrogen replacement therapy category of pharmaceuticals.

Signature Page

Signature: _____
Dale Bystrom, R.Ph.

Date: 6/30/02

Attachment-A

Dale A. Bystrom, RPh.
1929 Scenic Drive
Modesto, CA. 95355

Title: Director of Business Alliances, Longs Drug Stores
Vice President of PBM Services, Nex2, Inc.

Education: University of the Pacific School of Pharmacy, B.S. Degree in Pharmacy.
Graduated October 1968
Kellogg Executive Programs, Northwestern University, Illinois, 1992-93

Experience:

1966 - 1968	Intern Pharmacist, Longs Drug Stores California, Inc.
1968 - 1969	Staff Pharmacist, Longs Drug Stores Modesto, California, Inc.
1970 - 1979	Pharmacy Manager, Longs Drug Stores Carmel, California, Inc.
1980 - 1986	Store Manager, Longs Drug Stores Modesto, California, Inc.
1986 - 1988	General Merchandise Manager, Longs Drug Stores Walnut Creek, California, Inc.
1988 - 1990	Vice President of Marketing, American Drug Stores Oakbrook, Illinois
1991 - 1995	Director of Managed Care Pharmacy Services, Longs Drugs Walnut Creek, CA.
1995 – 1997	Vice President of Managed Care Services, Integrated Health Concepts PBM, a subsidiary of Longs Drug Stores California, Inc.
1997 – 1999	General Manager, RxAmerica PBM Salt Lake City, UT.
1999 –	Director of Business Alliances, Longs Drug Stores Walnut Creek, CA.
1999 -	Vice-President of PBM Services, Nex2, Inc., Salt Lake City, UT.

Professional Activities:

Member of American Pharmaceutical Association
Member of California Pharmaceutical Association
Member of Hawaii Pharmaceutical Association
Member of Pharmacy Advisory Committee for California Medi-Cal
Member of American Managed Care Pharmacy Association
Member of National Association of Chain Drug Stores
Member of National Council of Prescription Drug Programs

Significant Recent Career Achievements:

Development of Nex2's PBM Network:

As Vice President of PBM Services for Nex2, Inc., Dale developed the strategy and implemented the contracting process to build the national PBM network for Nex2. As of February 2002 Nex2's contracted network of thirteen national PBMs consisted over 260 million covered PBM

lives with 60 months of their associated prescription histories. There are fifteen additional PBMs in Nex2's contracting pipeline.

Development of Longs' Internet Strategy:

Dale led the team effort resulting in the development of the Internet strategy for Longs website, Longs.com. and its associated service offerings. Subsequent to the establishment of Longs.com, Dale has developed business alliances linking Longs.com with numerous health care organizations for which Longs is a pharmacy provider.

Merger of IHC with RxAmerica:

Dale developed the strategy for and implemented the merger of Longs' subsidiary PBM, Integrated Health Concepts, with RxAmerica, a PBM owned by American Stores / Albertsons. After acting as Co-General Manager of RxAmerica for two years Dale lead the analysis and assessment efforts leading to Longs' acquisition of Albertson's equity in RxAmerica. RxAmerica is now a wholly owned subsidiary of Longs Drug Stores.

Development of Integrated Health Concepts (IHC):

IHC was conceived and developed as a subsidiary company for Longs by Dale in May of 1995. IHC was a fully functional Pharmacy Benefits Management Company (PBM) with over one million lives under IHC program management. IHC administered a pharmacy network comprising over 45,000 pharmacies nationally.

Chain Pharmacy Network Contract Administration:

As Vice President of Managed Care Pharmacy for Longs Drug Stores, Dale negotiated and administered all third party contracts for Longs national participation.

Industry Advisory Panel Participation:

- State of California Medical advisory task force
- Health Net
- Blue Cross of Calif.
- Cigna of Northern California
- Blue Shield of California
- Parke-Davis
- Warner Lambert
- Merck
- Lilly